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Evaluation of international standards for ECG-recording and storage for use in tele-medical services

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Table of Contents

1 Abstract

This report is written to clarify which of the international standards for ECG recordings that can be used in tele-medical services, where the recordings should be transmitted by wireless telecommunication facilities and finally stored as information integrated into the patients Electronic Health Record (EHR).
Some principals for recording, transmission and storage of digital vital signs parameters are highlighted and important aspects of wireless communication of recorded signals from biomedical sensors are described, in order to understand the significance and differences in the storing formats to be used.
Even if most of the relevant standards are not yet ratified (the last meeting in ISO TC 251 WH6 was held in October 2005), the actual international standards SCP-ECG, MFER, FDA-XML and DICIOM are defined and already widely adopted.
In this report, these standards are briefly described and evaluated with respect to possible use in tele-medical services, and recommendations are given in order to obtain a reliable and secure communication solution.
Requirements for integration of the ECG file formats into the EHR are briefly described, and it is given some recommendations for actual standards to be used in future solutions.

2 Introduction

Today, ECG-equipment is storing the recoded measurements in many different manufacture dependants proprietary data formats. Despite intense influence from the hospitals and other users to achieve a common data format which every manufactory should use, it is difficult to adopt a common solution based on international standards for Vital Signs Monitoring.

Several international actions have been taken in order to develop standards concerning vital signs monitoring, however, there are a lack of clear recommendations and approved standards. In May 2003 the International Telecommunication Union (ITU) tried to start up a coordinated work by establishing the e-health Standardization Coordination Group (eHSCG)[1] and started the work on e-health standardization framework in SG16. It was an intention that ITU, ISO (particularly the TC251), CEN, IEEE, HL7 and DICOM should strengthen their cooperation on e-health. It is still a challenge to achieve interoperability in tele-medical systems, and it is yet not published any new information from this standard initiative.

In this report, evaluation of the published international standards SCP-ECG, MFER, FDA-XML, DICIOM are carried out because those standards to some extent are adopted by different manufactures, and they are all supposed to have a great impact on the adoption of standards for vital signs monitoring solutions.

When new tele-medical services are developed, it should be a golden opportunity to develop solutions based on well known international standards. However, the standards are not primarily intended for tele-medical services or the corresponding challenges in wireless and mobile communication, which require special precautions based on the telecommunication principles.

This report will focus on the international standards mentioned for ECG-recording formats, and will evaluate the data formats from a tele-medical point of view. The advantages and drawbacks for the standards evaluated will be highlighted correspondingly, and based on this; recommendations are given with respect to suitable implementations.

[1] http://www.itu.int/ITU-T/worksem/e-health/

3 Principals for digitalization of Vital Signs monitoring solutions

Vital signs monitoring is an expression used for solutions where different types of biomedical signals are measured on a patient, where the trend today is to perform such measurements by wireless technology as a tele-medical solution and the use of wireless biomedical sensors.

One important parameter in vital signs monitoring is ElectroCardioGraph (ECG), which is measurements of the electrical activity of the heart, normally sensed by the use of surface electrodes mounted on the patients' skin.

Normally this is done with several electrodes placed at predefined locations in order to obtain 12-lead ECG recordings as a standard procedure performed at hospitals.

For long-time ECG-recordings such as a "Holter-monitoring" solution, the patient can be wearing a recording unit for 24 or 72 hours usage, and some units can perform up to 7 days usage. The patient will normally have several electrodes sticked to the chest, mostly used is 5 electrodes as a 2-lead monitoring solution.

All ECG units have today incorporated a digitalization of the recorded curves. Principally this is performed by amplifying the analogue signal measured between two electrodes, and converting this signal to digital values. Typically the analogue signal is within ± 2 mV.

3.1 Sampling interval (frequency)

According to the "ACC/AHA Guidelines for ambulatory electrocardiography"[2], the digitalization should be performed with a minimum of 125 samples/sec and a minimum of 8 bit resolution of the sampled values. For arrhythmia analyses it can be necessary to have sampling frequency of 1000 s/sec (up to 2000 s/sec), and normally ECG-equipment is using a signal resolution of 10 or 12 bit. Figure 1 shows the two important parameters, Sampling interval and Resolution.

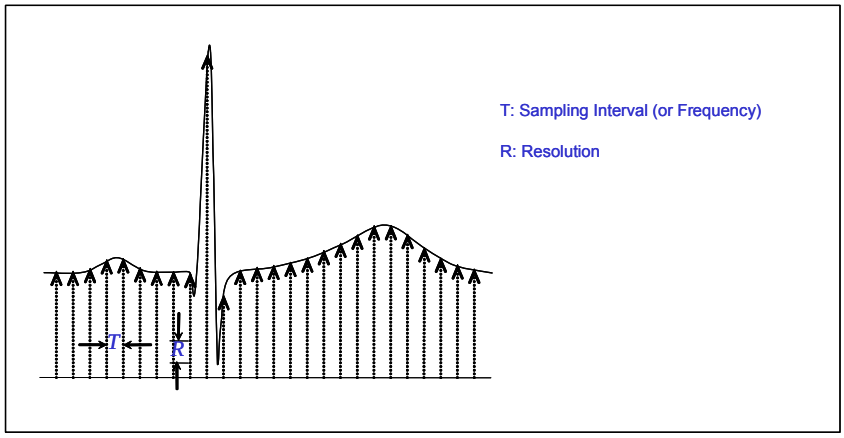


Figure 1Sampling of analogue ECG-curve, where important parameters as Sampling interval and Resolution are shown[3].

[2] M. H. Crawford, "ACC/AHA Guidelines for ambulatory electrocardiography", Journal of the American College of Cardiology, vol. 34, pp. 912-48, 1999.
[3] WD TS11073-90201, 2004-10-20. Health informatics — Medical waveform format — Encoding rules (MFER)

The recording equipment need to specify the two parameters T and R in the digital file of the recorded parameters in order to obtain correct representation of the analogue signals.

3.2 Signal Resolution

When the analogue signals are digitized, the analogue to digital converter normally will need a “ground” reference for the measurements, whereas the amplified signal will be within limits that for instance can be 0 – 4 Volts. This gives a digital representation of the recorded curve which can be within 0 – 4095 for a 12 bit resolution system. This could be given by a binary code, decimal value (ASCII value) or by a hexadecimal value (Hex-code) as indicated in Table 1.

Table 1Representation of measured analogue values and their corresponding digital values

Measured analogue value	Amplified Analogue value	Binary code	Decimal value (ASCII-code)	Hex-value
+2,0 mV	4,0 V	111111111111	4095	0x0FFF
+1,5 mV	3,5 V	111000000000	3584	0x0E00
+1,0 mV	3,0 V	110000000000	3072	0x0C00
+0,5 mV	2,5 V	101000000000	2560	0x0A00
0,0 mV	2,0 V	100000000000	2048	0x0800
- 0,5 mV	1,5 V	011000000000	1536	0x0600
- 1,0 mV	1,0 V	010000000000	1024	0x0400
- 1,5 mV	0,5 V	001000000000	512	0x0200
- 2,0 mV	0,0 V	000000000000	0	0x0000

Table 2 Comparison of digital resolution and incremental resolution for an analogue signal of ± 2 mV

Digital resolution Number of bits used	Decimal values Number of different values	Incremental Resolution µv/ bit
8 bit	256	15,625
10 bit	1024	3,906
12 bit	4096	0,976
16 bit	65536	0,061

In Table 2 the numbers of bits used for the digital representation of the sampled values are compared to the incremental signal resolution. With a 12 bit code, the least significant bit will have a value of approximately 1 µVolt (0,976µV), and when a normal ECG signal is recorded with an R-wave of 1 mV magnitude, this wave is represented by approximately 1000 digital incremental values (1000 / 0,976). If, however, an 8 bit code is used, this resolution will be limited to only 64 digital incremental values (1000 / 15,625). This resolution factor is of importance to achieve a good signal quality when arrhythmias are automatically detected by a software algorithm, but those resolution differences can hardly be recognized when the recorded curve is displayed on a screen or printed out.
However, the resolution parameter, R, is an important code to be defined in order to show the recorded curve with a correct resolution in the viewer program (software application).

3.3 Waveform representation

In the actual international standards, the digital representations of the digitized values recorded are given in different systems for the waveform representation as shown in Table 3.

Table 3 Representation of the digitized values in the actual International standards

International Standard	Waveform representation	Example (1.0 mV value)
SCP-ECG (in standard format, not compressed format)	binary files (16 bit signed words, Hex-representation with low-bit+high bit)	00 0C
MFER (by default, but different formats can be used)	Signed 16-bit integer	00001100 00000000
FDA-XML	ASCII-code	3072
DICOM	Signed 16-bit integer	00001100 00000000

If other signals than ECG is to be measured, with other type of units to be used, this has to be defined in the waveform representation. An overview of *Unified Code for Units of Measure* can be found at the web-page of Institute for Health Care and Indiana University School of Medicine[4], which is based on the ISO 2955-1983, ANSI X3.50-1986, and HL7's extensions called “ISO+” and the European standard ENV 12435.

3.4 Base64 encoded ECG waveforms

Some proprietary ECG-systems are using base64 encoding for the waveform representation, and typically this is used in some Philips systems[5]. Philips XML ECGs was first introduced in the cardiograph systems PageWriterTouch and the IntelliVue Bedside Monitor/Information Center. Philips Medical systems has been active member in developing the XML-format in the HL7-V3 committee. In addition to the proprietary Philips XML-format, it is possible to export or convert the files into standard FDA-XML format[6].

Base64 is a data encoding scheme whereby binary-encoded data (0-1) is converted to printable ASCII characters. It is defined as a MIME content transfer encoding for use in internet e-mail, and is a type of encryption algorithm[7].
The only characters used are the upper- and lower-case Roman alphabet characters (A-Z, a-z), the numerals (0-9), and the "+" and "/" symbols, with the "=" symbol as a special suffix code.
ABCDEFGHIJKLMNOPQRSTUVWXYZabcdefghijklmnopqrstuvwxyz0123456789+/
Specifications for base64 are contained in RFC 1421 and RFC 2045.
The scheme is defined only for data whose original length is a multiple of 8 bits, a requirement met by most computer file formats. The resultant base64-encoded data has a length that is approximately 33% greater than the original data, and typically appears as seemingly random characters.

[4] http://aurora.rg.iupui.edu/~schadow/units/UCUM/ucum.html#para-39
[5] http://www.openecg.net/member/portal.pl?c_header=Other%20Relevant%20ECG%20Formats;selected=Philips%20XML%20ECG
[6] http://www.medical.philips.com/main/products/cardiography/xml.html
[7] http://en.wikipedia.org/wiki/Base64

To convert data to base 64, the first byte is placed in the most significant eight bits of a 24-bit buffer, the next in the middle eight, and the third in the least significant eight bits.

It is worth notifying that only the proprietary Philips-XML format uses the Base64 encoding schema, this is not defined in the FDA-XML standard which uses ordinary ASCII representation of the sampled values.

3.5 Huffman encoding

Huffman coding is an entropy encoding algorithm used for lossless data compression. The term refers to the use of a variable-length code table for encoding a source symbol (such as a character in a file) where the variable-length code table has been derived in a particular way based on the estimated probability of occurrence for each possible value of the source symbol. It was developed by David A. Huffman as a Ph.D. student at MIT in 1952, and published in A Method for the Construction of Minimum-Redundancy Codes[8].

The Huffman encoding can be used with calculated optimalization parameters in order to obtain a better compression capability. Huffman encoding is used by the SCP-ECG standard in order to compress the file-length of a recorded ECG-file.

[8] http://en.wikipedia.org/wiki/Huffman_encoding

3.6 Recording and storage of standard ECG-leads

During normal EKG-recordings, a standard 12-lead recording procedure can be a paper-recording printout showing 4 leads at a time, and with 3 sequences of approximate 5 sec, which gives a total of 12 leads recorded (each with a 5 sec recording time). Alternatively there can be more channels shown as in the Figure 5 that displays 6 simultaneous channels. There exists a standard representation of the channels given by "LEAD-names", whereas the standard 12-lead ECG-recording is given by lead I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5 and V6. There are defined a standard nomenclature for actual ECG-leads in the standard ISO/IEEE 11073-10102 Point-of-Care.

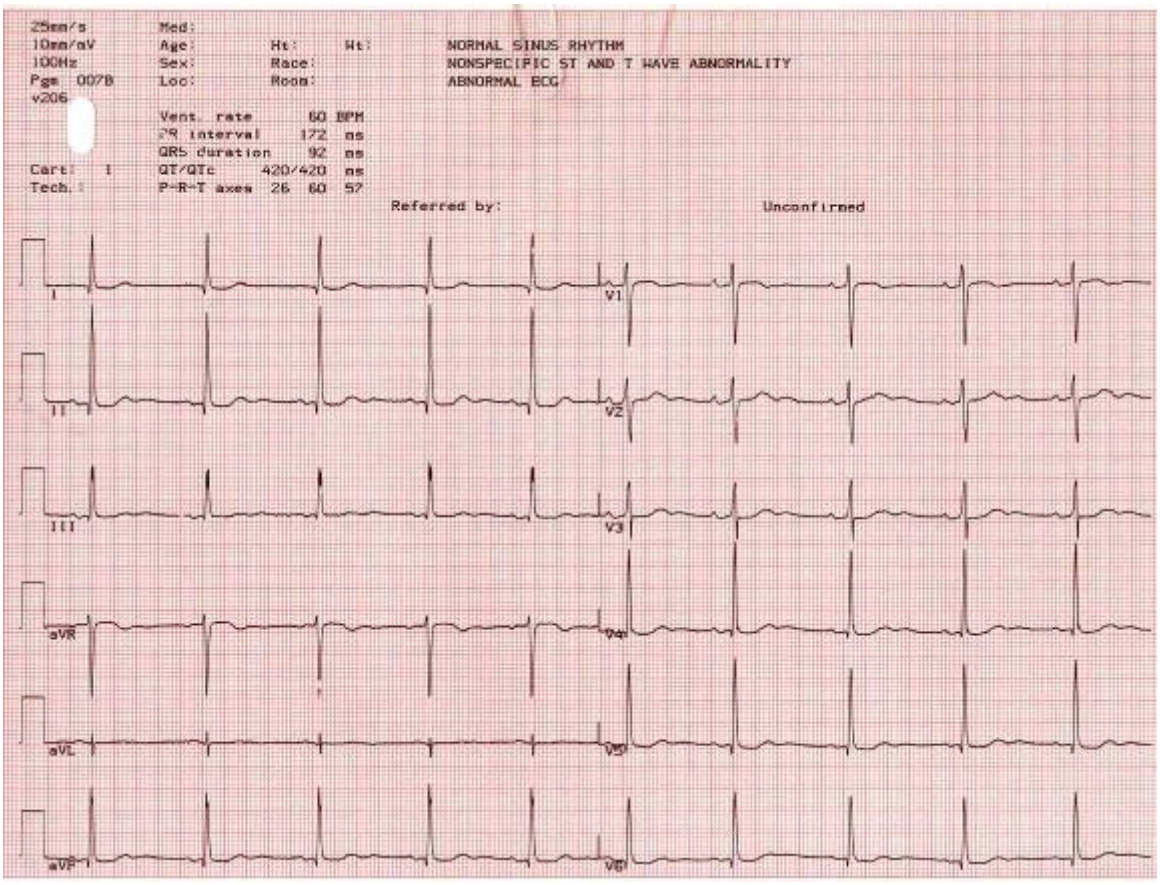


Figure 2 The picture is a scanned image of a standard printout from a 12-lead ECG recording system.

In Figure 2 the ECG-recordings is shown as an image file, which will be the situation if the actual ECG-recordings are stored in an image file format, as described in chapter 4.5.

It is important to obtain time-synchronization between the different channels in order to view the recordings with a correct time-series. This can be done in different ways when the recorded sampled values are to be stored digitally. The FDA-XML format described the time series for each lead individually, and the viewer application will have to display the recorded curves correctly with a synchronized start of the recording.

In the MFER-proposal, this is obtained with the definition of a number of frames, each consisting of a number of Channels having the sampled values stored in Data Blocks which is given within a number of Sequences, as shown in Figure 3. This opens up for longer time-

series to be recorded, and the number of leads can be defined as desired, for instance in Holter recording systems with only 2 leads and almost a continuous recording.

It is a need, because of different formats used for storing the recorded time-series, to take special attentions when one format of the recordings are to be converted into another format.

3.7 Annotations

For arrhythmia detections it is important to measure interesting findings with respect to the actual curve-form recorded. Most manufactures can deliver automatic arrhythmia detection software (with proprietary algorithms) and with different functionality. However, the actual annotations as the R-wave detection, is standardized in the use of abbreviations, given by the international standard ISO/IEEE 11073-10101 Point-of-Care, see chapter 5.1. Normally, the actual annotations are stored separately with corresponding pair of values: Time of the event and the annotation code. It is then possible to store the annotations in a separate file, or it can be implemented into the ECG-recording file as separate codes.

However, those storage formats can differ between the actual international standard for ECG-recording, and is more deeply described in evaluation of the actual standard.

4 Existing and proposed international standards for ECG-recording file formats

4.1 CEN ENV 1064 (SCP-ECG) (working draft 2004)

CEN/TC 251 European Standardization of Health Informatics, has established several working groups[9].
The Working Group IV - Technology for Interoperability, is focusing on topics of medical imaging and multimedia, international standards and medical device communication in integrated healthcare.

Important subjects are:

- Intercommunication of data between devices and information systems
- Integration of data for multimedia representation
- Vital Signs Information (VITAL)
- CEN TC251 PT5-007 - prENV1064 Draft Standard Communications Protocol for Computer - Assisted Electrocardiography (SCP-ECG)

The SCP-ECG proposed standard is a result of an EU supported project that European, American and Japanese Manufacturers and Users have jointly worked and agreed on (1989-1990). In 1993 it became a European ENV, later positively balloted within AAMI (AAMI EC71), and is currently a new work item proposal to IEC TC/SC 62 WG1 and ISO TC215[10].

At 05th of March 2004 the draft IEC 62D/60601-2-53/Ed.1 Standard communication protocol for computer assisted electrocardiography (62D/499/CD) was submitted to the national committees of the IEC and ISO for their comments[11].

The SCP-ECG standard (CEN ENV 1064) defines the structure of the Medical Data Information Base (MDIB) that contains the managed medical objects as defined in the Domain Information Model. These managed medical objects represent the ”real world instances" of the application domain.

The latest proposal from CEN/TC 251 is prEN 1064:2005 (E), Health informatics — Standard communication protocol — Computer-assisted electrocardiography. The important aspect of the standard is to specify data format for transferring ECG reports and data from any vendor’s ECG-recorder system to any other systems or to a central management system, and should allow standard data transfer of digitized ECG data and results between various computer systems.

The standard specifies the common conventions required for interchange of specific patient data (demographic), ECG signal data, ECG measurement and ECG interpretation results. The content and structure of the information are defined in order to be a general and interoperable standard.

The following information is from the introduction chapter:
Under the standard communication protocol (SCP) the contents and format of the ECG waveform data and the measurements from ECG devices of different manufacturers are not

[9] http://www.centc251.org/
[10] http://www.openecg.net/HomeFrame.html
[11] http://www.tc251wgiv.nhs.uk/pages/docs/wgiv04_21.zip

expected to be identical. As a result, the determination of the suitability of a device and/or system for any particular application remains with the user/purchaser. The following possible uses of ECG records require special attention:

- *serial comparison of ECGs and interpretations;*
- *plot formats of ECGs;*
- *maintaining audit trail of edits;*
- *bi-directional communication and remote query.*

The user is cautioned to make sure that the data contents and format of the waveform data, measurements, and the interpretive statements meet his or her specific needs. If more than one type of ECG devices and/or database management systems are interconnected, the user is also advised to verify with the manufacturers that the data from different systems are compatible with each other and with the user's needs.

The standard has also defined a minimum set of control and query messages for the interchange of ECG data between a recording unit and a viewer solution.

The SCP-ECG standard has not been designed to exchange specialized recordings of intracardiac potentials or of the so-called Holter or other longterm ECG recordings made for monitoring cardiac rhythm. The standard also does not address exercise ECG recordings.

ECG computer processing can be reduced to 3 principal stages:

1) *data acquisition, encoding, transmission and storage;*
2) *pattern recognition and feature extraction, i.e. ECG measurement;*
3) *diagnostic classification.*

In each of these stages there are important needs for standardization and quality assurance testing. The scope of the standard is confined to the first of these three stages.
The various data sections that shall be transmitted by means of the standard ECG communications protocol is defined in Clause 5 of the document. Minimum requirements for data encoding and compression are also defined (Clause 6 of the document).
The compliance categories (defined in Annex B of the document) provide users and manufacturers of ECG devices and/or systems with a relatively simple codification of SCP-ECG related features and information content that may be provided by a specific device.

The SCP-ECG standard uses binary files (16 bit signed words) for storing the actual samples. In order to obtain a compact file structure, the SCP-ECG standard describes compression solutions to be used. An encoding method where variable length codes are used in such a way that the shortest codes are used to encode the most frequently occurring data is called Huffman encoding.

The SCP-ECG protocol was designed to handle data which may be compressed and encoded by different methods:

a) pure redundancy reduction;
b) "high SCP-ECG compression".

When Huffman encoding is used, the ECG-recording system needs to have implemented analyzing software which is able to detect a "reference beat". This beat is then subtracted from the recorded curve before the compression algorithm calculates a down sampled curve. A computer system receiving the transmitted SCP-ECG files should be able to handle the actual compression method, which should be implemented in a viewer application.

4.1.1 ECG Binary File Format (from Subclause B.3.3)

Each test ECG shall be provided with the following information:

1) A text file (***.EC2) containing:
   i) comma delimited descriptors for each lead of ECG data (which may be more leads or less leads than the typical 8 stored for a resting 12-lead ECG),
   ii) the total number of samples for each lead,
   iii) the sample rate (per second) or sample interval (microseconds),
   iv) and the number of nanoVolts per least significant bit.
2) Binary files (***.EC0, ***.EC1) with ECG data stored as16 bit signed words, stored in Intel format (low-byte, high-byte). The sequence of the samples (S1, S2 … Sn) for leads (L1, L2 … Lm) is: S1L1, S1L2 … S1Lm, S2L1, S2L2 …SnL1, SnL2 … SnLm

EXAMPLE The following example is for 8 ECG leads, all identical to each other, with alternating samples of +/- 1,0 mV for each lead. In this case, +/- 1 000, hexadecimal values of 03E8 and FC18.

***.EC2 - Text file contains the following:
Leads: I, II, V1, V2, V3, V4, V5, V6
5 000 samples per lead; 500 samples per second; 1 000 nanoVolts per LSB.
***.EC0 or ***.EC1 - Binary file (in Hexadecimal for each byte):

Table B.2 - Example for 8 ECG leads

		Leads								
		I	II	V1	V2	V3	V4	V5	V6	
Bytes:	00 to 0F	E8 03	E8 03	E8 03	E8 03	E8 03	E8 03	E8 03	E8 03	Sample 1
	10 to 1F	18 FC	18 FC	18 FC	18 FC	18 FC	18 FC	18 FC	18 FC	Sample 2
	20 to 2F	E8 03	E8 03	E8 03	E8 03	E8 03	E8 03	E8 03	E8 03	Sample 3
	30 to 3F	18 FC	18 FC	18 FC	18 FC	18 FC	18 FC	18 FC	18 FC	Sample 4
	40 to 4F	E8 03	E8 03	E8 03	E8 03	E8 03	E8 03	E8 03	E8 03	Sample 5
	50 to 5F	18 FC	18 FC	18 FC	18 FC	18 FC	18 FC	18 FC	18 FC	Sample 6

4.1.2 Formatting options for the ECG data[12]

There are principally four options for formatting the ECG data.

1. *Uncompressed Raw Data*
   The ECG raw data need not be compressed.

2. *Lossless redundancy reduction*
   The ECG may be lossless compressed by redundancy reduction, e.g. using first or second order sample differences.

3. *Lossless redundancy reduction with Huffman encoding*

4. *SCP ECG High Compression (lossy)*

   For ECG high compression ECG data analysis is necessary. From the ECG data a reference beat needs to be computed and pointers for localization and beat typing information have to be derived. Without the SCP overhead information compression ratio for the ECG data of up to 25 may be obtained. Typically a complete high compressed record has a length of 6 to 8 kBytes.[13]

[12] http://www.openecg.net/tutorial2/tutorial2_SCPformating.html
[13] http://www.openecg.net/tutorial2/tutorial2_SCPformating.html

A global overview of the SCP-ECG data structure is presented in the Table below[14]:

CRC CHECKSUM
SIZE OF THE ENTIRE SCP-ECG RECORD
POINTERS TO DATA AREAS IN THE RECORD ("Table of content")
HEADER e.g. PatID, Device ID, Recording ID (Time stamp etc.)
ECG Data in optional formats without/with (selectable) compression methods
Various types of processing and overreading results

The SCP-ECG standard is highly promoted by the OpenECG consortium: http://www.openecg.net/ . There is a lot of information available at the website, with file converters and free software.

4.1.3 File viewers

A free SCP-ECG viewer can be downloaded from the web-site:
http://www.dclunie.com/pixelmed/software/

This programme was developed by David A. Clunie DBA PixelMed Publishing as a contribution to “The 2nd OpenECG workshop” in Berlin, 1-3 April 2004 contest:
http://www.ercim.org/publication/Ercim_News/enw58/chronaki.html

4.1.4 Evaluation of the standard

The SCP-ECG standard is becoming a European standard for storage and exchange of ECG-recordings, and it is expected that all manufacturer need to implement a file converter in order to be able to export files supporting this standard.
This standard is intended for use in an ordinary 12-lead ECG-recording system, and can be difficult to adopt for a long-time ECG-recording solution like a Holter monitoring system and in exercise recording systems for sports medicine.

Because of the compression methods, the standard will require a considerably amount of processing time and capacity, which can be hard to achieve within wearable systems intended for a tele-medical framework.

From a central ECG-file storage system, there should be possibilities to incorporate necessary file exporting software with functionality of converting the stored recordings from a proprietary file format to the SCP-ECG format. Such solutions can give possibilities for secure messages transfer from a vendor proprietary ECG-file storage system to actual electronic health record systems at a hospital.

Because of the file compression methods used in the SCP-ECG format, the file size is relatively small, and could easily be sent from one hospital to another as a secure message in the National Health Network.

[14] http://www.openecg.net/tutorial1/index.html

4.2 ISO/WD 11073 90201 (MFER) (working draft 2004)

The proposed standard ISO TS11073 90201 was prepared by Technical Committee ISO/TC 215, TC Health informatics, and current version is of 2004–10-20, defined as Health informatics — Medical waveform format — Encoding rules (MFER)[15].

It is based on the work from a Japanese initiative in the MFER Committee (Chairman Masaaki Hirai, Nihon Kohden), where the aim was to develop a universal standard description format for medical waveforms, in order to make physiological information easy to handle and separated from other information as the patient information and exsamin information. The intention was to describe a solution which was simple and easy to install, and at the same time harmonized with other standards[16].

The standard comprises of different levels of the protocol[17]:
(1) Level 1
Definitions at level 1 are basic definitions, which are divided into ordinary rules and rules for precise encoding.
(2) Level 2
Definitions at level 2 are supplementary definitions. They may be used as required but it is desirable to make the supplementary definitions with a host protocol, if they can be defined with the host protocol.
(3) Level 3
Definitions at level 3 are extended definitions, which are desired to be used as limited as possible. Items of these extended definitions may considerably affect the system with regard to privacy, security, etc. thus, sufficient considerations should be taken in designing them.

4.2.1 Scope of the standard

Medical waveform is defined as a time sequential data which are sampled by A/D converter or transmitted from medical equipment. This standard specifies how medical waveforms, such as Electrocardiogram, Electro-encephalogram, Spirometry waveform etc., are described for interoperability among healthcare information systems.

This standard does not include lower layer protocol for message exchange. For example, critical real time application like a patient monitoring system is out of scope and this is a question of implementation issues.

4.2.2 Basic specifications

Medical waveform data described in accordance with the MFER consists of Sampling attributes (Sampling interval and Sampling resolution as shown in Figure 1), and Frame attributes (as shown in Figure 3) with addition of other supplemental information.

The recorded file is described within a number of frames, each consisting of a number of Channels having the sampled values stored in Data Blocks which is given within a number of Sequences. The actual sampled values can be stored in different data formats, with Signed 16-bit integer as default type.

By default MFER does not use data compression methods because of the binary data format used and, the standard gives relatively compact and small data-files. However, general compression solutions can be used for compression of binary files as ZIP and TAR.

[15] ISO/TC 215/WG2.1 WD 11073-90201 Health informatics — Medical waveform format — Encoding rules (MFER), 20.10-2004.
[16] Medical waveform description Format Encoding Rules, MFER Part I, Version 1.01-2003.
[17] At the time of writing this report (January 30th 2006), only the document specification at Level 1 is available.

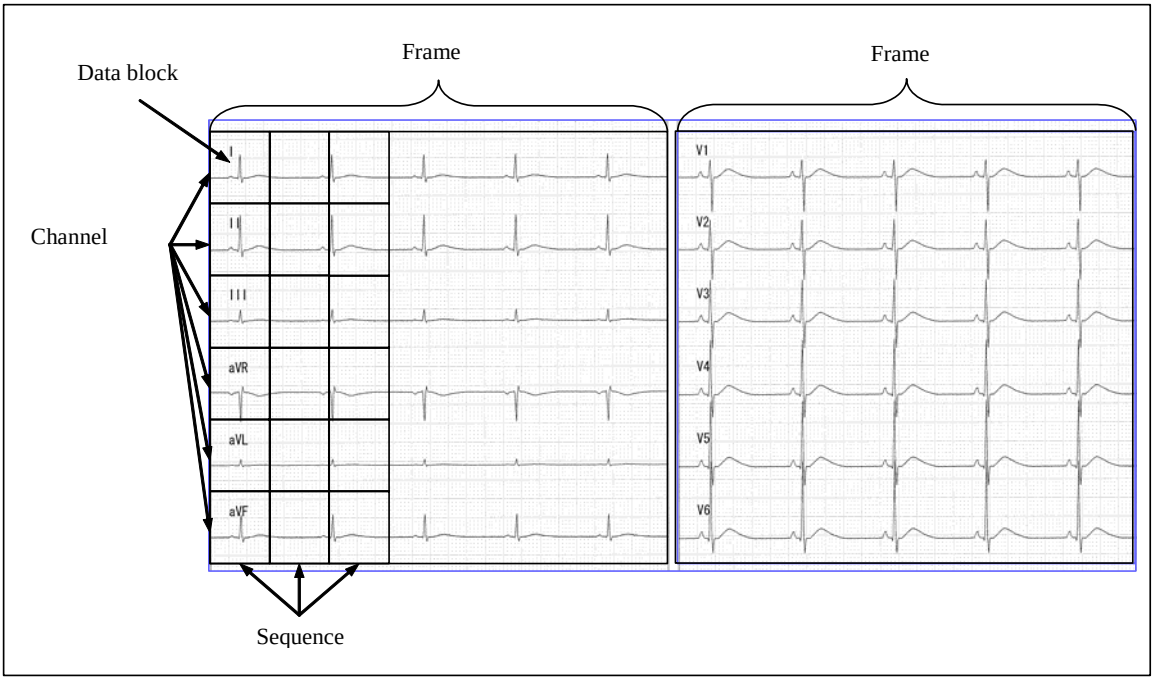


Figure 3 MFER representation of ECG-recording by dividing the recorded information into Frames consisting of Channels having the sampled values stored in Data Blocks which is given within a number of Sequences[18].

The header and waveform data format is based on the encoding rules which are composed of the type (tag), length and value (TLV), with a Frame consisting of a Header section and a Payload section with the actual waveform data (samples) as seen in Figure 4.

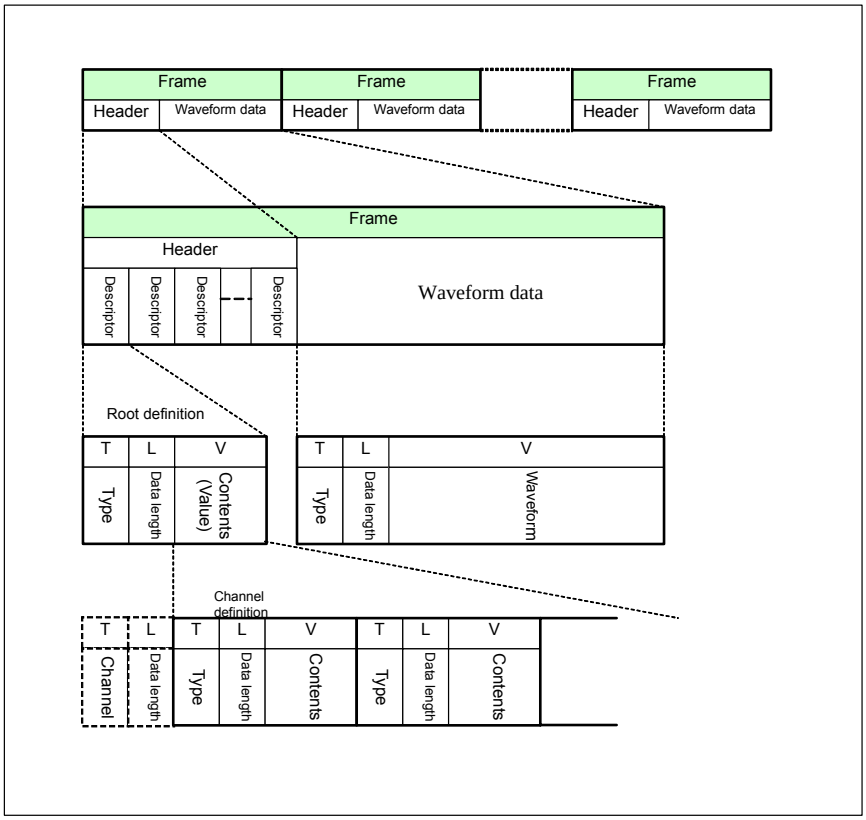
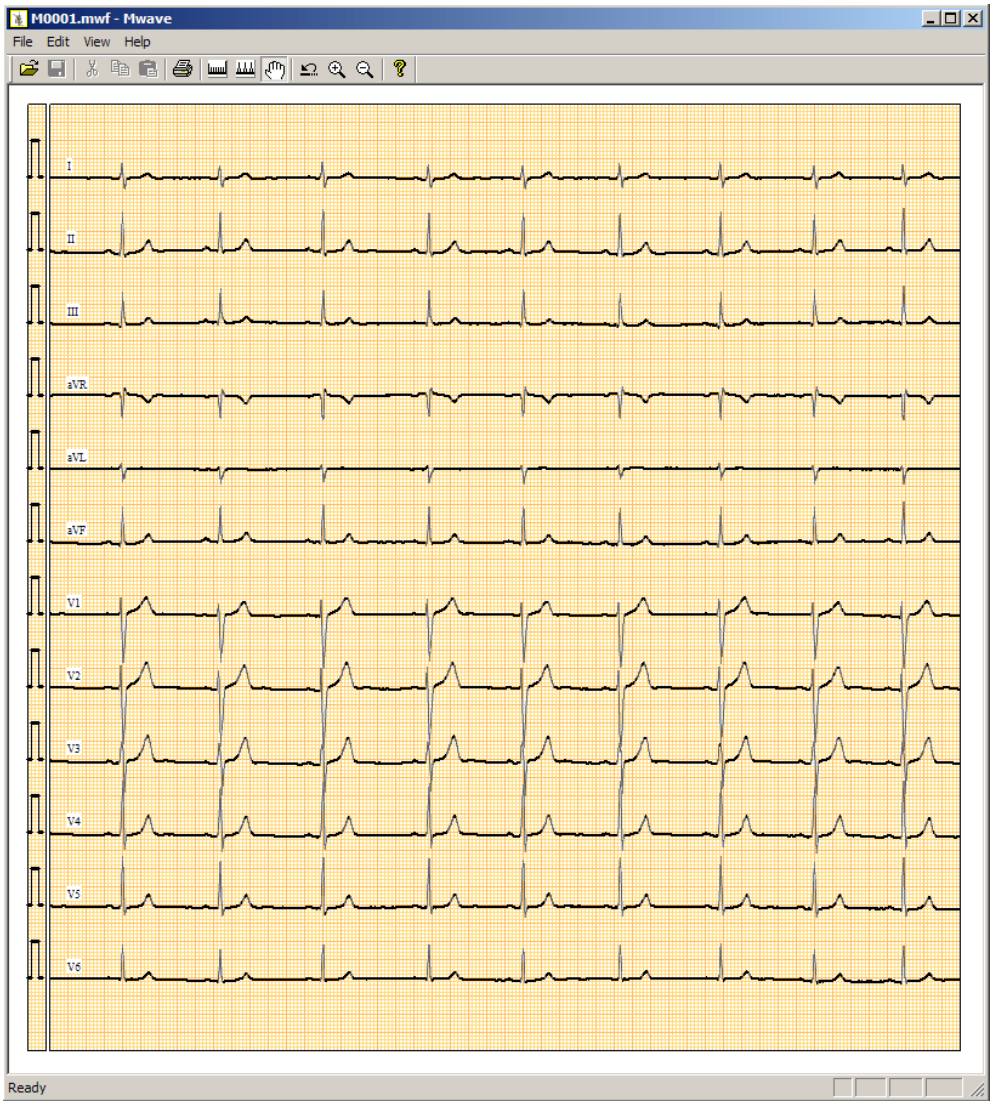


Figure 4MFER Encoding format with a file header and waveform data payload[18].

[18] ISO/WD 11073 90201- Health informatics — Medical waveform format — Encoding rules (MFER)

4.2.3 File viewers

Some information is available at the MFER web-site: http://ecg.heart.or.jp/En/Index.htm
The MFER viewer v 1.11 is a simple tool to display ECG recordings stored in the mwf format, and makes it possible to measure simple curve distances.



4.2.4 Evaluation of the standard

MFER uses the header section to identify the contents. The header describes sampling conditions, frame alignment and other related information. Descriptors include the root definition which covers all encodings and channel definitions which cover encodings for relevant channels. The format description is clear and understandable, and could easily be implemented in other software solutions.

It is used a compact binary format with a compact code in the header section, which gives relatively small file sizes.

Based on this data structure format, the standard can be used both for a standard 12-lead ECG-recording and is also suitable for fewer channels (1-3 channels) long-time Holter recording systems.
The format defined (mwf) can also be used for several defined types of Vital Signs, and the standard describes different waveform types to be used (electrocardiogram, sound, pulse, monitoring, magnetocardiogram, electroencephalogram etc.) which makes this format extremely open and flexible.

In the supplementary description at Level 2, tags represent waveform-related information such as measurements are defined. At this level there might be possible to implement beat annotations, however, the question of annotation is still under considerations[19].

The extension tags at Level 3 are for the extended supplemented information with MFER. This information should be represented with the same encoding schema as other standards based on the HL7 Reference Information Model.

Because of the compact binary coding schema with a relatively small file header and a relatively large data payload, the MFER format can be used in wireless ECG-systems in a tele-home-care framework.

[19] Personal information given by Masaaki Hirai, December 2005

4.3 ANSI/HL7 V3 Annotated ECG (FDA_XML) (accepted standard 2004)

The Annotated ECG (aECG) HL7 standard was created in response to the FDA's digital ECG initiative introduced November, 2001.
The aECG standard was created by HL7's Regulated Clinical Research Information Management (RCRIM) in response to the FDA's need. It passed final balloting in January, 2004, and was accepted by ANSI May, 2004[20], and is published as: ANSI/HL7 V3 ECG, R1-2004, Health Level Seven Version 3 Standard: Regulated Studies - Annotated ECG, Release 1 (new standard): 5/6/2004[21].

- **aECG** – Annotated ECG. The name given to a file or message conforming to HL7's "Annotated ECG" standard. It contains one or more *series* of ECG waveforms pertaining to a *relative timepoint* and a set of derived ECG findings for that timepoint.

The background for introducing this standard was FDA´s need to review ECG-recordings in clinical trials, and it is therefore in September 2005 launched a new ECG Warehouse[22]. The FDA is interested in improving the evaluation of specific drug-induced cardiac toxicity by evaluating ECG waveform data with detailed, sponsor-generated annotations from the full spectrum of ECG devices including 12-lead standard ECG, Holter monitors, and implanted devices. A web-based system supports communication with the sponsor for uploading, receipt, validation, transformation, and warehousing of aECG source data. The warehouse enables the FDA to evaluate aECG source data for evidence of cardiac toxicity and the viewing tool allows reviewers to selectively display waveforms and annotations.

The ECG-warehouse is developed for sponsors and central laboratories which can subscribe to the Mortara E-Scribe ECG Warehouse, in order to perform submission, during an active study or as a long term archiving and study-metrics tracking solution[23].
However, it will be critical to have annotated ECG waveform data for those studies intended to definitively address the effects of a drug on ventricular repolarization[24].

Even though the aECG standard was created in response to the FDA's need to have ECG waveforms and annotations, it does not mean that it can not be used for other purposes

4.3.1 Data format structure

The FDA XML Data Format Design Specification (Revision C, April 2002) was an FDA specification (draft) covering the design for the waveform data format as well as the relevant submission information. This specification was passed from FDA to HL7 to be further developed and included in HL7 V.3 – Annotated ECG format.
HL7 V.3 Standard Development Model is based on an Object Oriented (OO) approach using Unified Modeling Language (UML), and all message models are derived from a Reference Information Model (HL7 RIM). A Refined Message Information Model (R-MIMs) is the source for defining messages and XML-Schemas, and a complex model aECG R-MIM is a fundamental basis for developing the XML structure for ECG-recordings.

[20] HL7 aECG Implementation Guide, 2nd Draft, October 5, 2004, Barry D. Brown & Fabio Baldini
[21] http://public.ansi.org/ansionline/Documents/Standards%20Action/Archives/2004%20PDFs/SAV3520.pdf
[22] http://www.fda.gov/cder/meeting/aECG/default.htm
[23] https://www.ecgwarehouse.com/htmdocs/about_us/index.html
[24] ECG Warehouse Rollout Meeting, September 30, 2005, Norman Stockbridge, Division of Cardiovascular and Renal Products, FDA

Principally all ECG-registrations reported to the ECG Warehouse needs annotations to be done by the sponsors, and those annotations are one of the important factors to be validated by FDA[20].
Because of these fundamentally integrated annotations, the HL7 v.3 specification for ECG-recordings is also known as *Annotated ECG in XML*.

Each ECG file will have a unique ID, (UID), containing a "root" object identifier (OID) and "extension". The OID is defined by ITU-T recommendation X.208 (ASN.1) and can be comparable to the DNS namespace. Organizations can obtain OIDs from IANA (http://www.iana.org), or request for a free UID prefixes for Medical Connections's from Dave Harvey, at http://www.medicalconnections.co.uk/index.html.
Each organization can obtain an OID prefix for its organization and create a way to manage OIDs for:

- Organizations
- People
- Places
- Things

The organization is responsible for defining a hierarchy like a namespace of Universally Unique Identifiers, UUIDs for computer-generated things like:

- aECG
- Series

4.3.2 XML-schema and structure

The XML format is defined in a corresponding standard XML-schema, as shown in the extraction of the XML-coding given below.

```
<?xml version="1.0" encoding="utf-8" ?>
- <!--  HL7 V3 (FDA) Annotated ECG - Dec 2003 Ballot format -->
- <AnnotatedECG xmlns="urn:hl7-org:v3" xmlns:voc="urn:hl7-org:v3/voc"
    xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
    xsi:schemaLocation="urn:hl7-org:v3 /HL7/aECG/2003-
    12/schema/PORT_MT020001.xsd" type="Observation" classCode="OBS">
  <id root="8fda4720-6c98-11d8-4823-116cff240029.xml" />
  <code code="93000" codeSystem="2.16.840.1.113883.6.12" codeSystemName="CPT-4"
    displayName="Electrocardiogram" />
  <text />
```

4.3.3 AnnotatedECG

The ECG waveform contains annotations for a particular relative timepoint called a "Region-of interest", RoI. Typically a series will contain all the waveforms and annotations for a single ECG. If multiple ECGs are contained within a single aECG file, a different series is used for each.

A sequence is an ordered list of values having a common code (or dimension). The sequence values are associated with other sequence values within a sequence set. For example, a 12-lead ECG series will contain a sequence for the timestamps at which the electrocardiograph sampled the lead voltages, and 12 other sequences containing the voltages measured at those times.

Time-series are defined using Date/Time Data–types defined by HL7-format specifying 4 digit year + 2 digit month + 2 digit day + 2 digit hour + 2 digit minute + 2 digit second + a separator "." and fractional of seconds.

Only one ECG context (TimepointEvent, ReferenceEvent, RelativeTimepoint) can be described in an aECG. Each aECG file represents supporting data for a particular assessment in the trial. Multiple findings can be derived from a single aECG (e.g. QT, RR, PR, etc.). Multiple aECGs can be used to derive a single finding (e.g. a single QT by averaging QTs from 3 ECGs for a single relative time point).

The annotations used by the FDA XML are defined by ISO/IEEE 11073-10101 Point-of-Care.

4.3.4 Waveform representation

In the FDA XML standard, sampled values for the recorded waveform is represented by Integer values in ASCII format. The values are given sequentially separated by a space. In the definitions parameters like the scale factor and sampling frequency are defined.

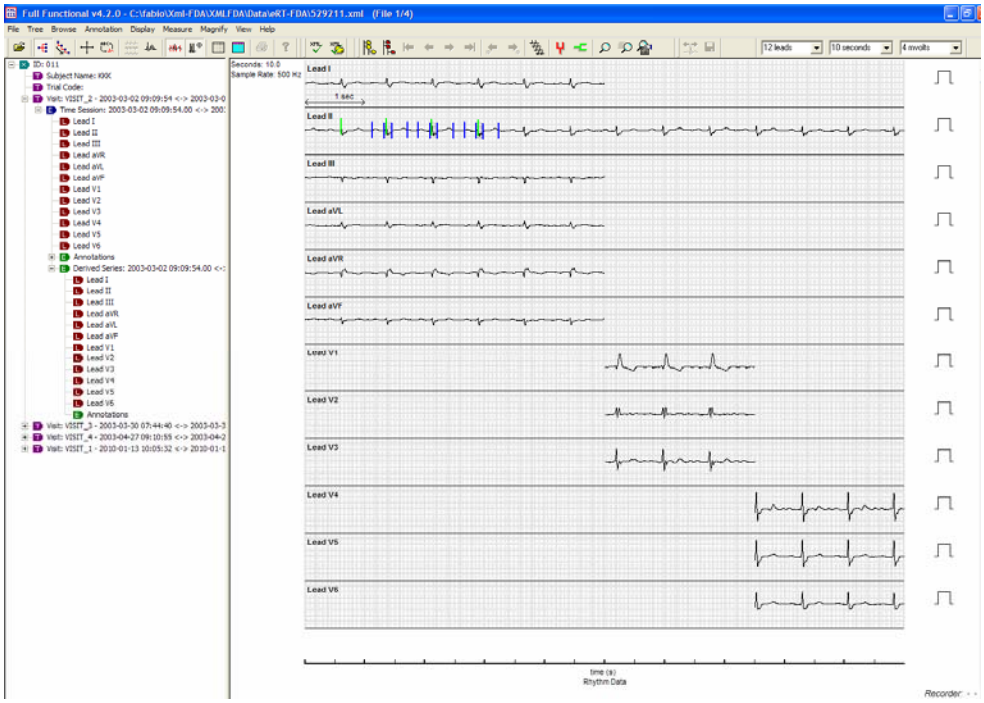


Figure 5 The figure shows the AMPS XML Viewer, which can display and validate XML FDA aECG files[25].

4.3.5 Evaluation of the standard

This standard is recommended by FDA to be used for submission of ECG recordings to the ECG Warehouse, and us thus supposed to be implemented by most vendors.
The format allows for a vide range of annotations, and the file can contain several time-series of recorded signals. It can be used both for a standard 12-lead ECG recording and for long-time recordings as a "Holter monitor" solution.
It should be easy to adopt this file format within the secure ebXML messages recommended for the national health network in Norway.
However, because of the XML- structure, this file format is relatively large in the file-size.

[25] http://www.amps-llc.com/

4.4 ENV 12052 Medical Imaging, DICOM Supplement 30 - Waveform Interchange (implemented 2001)

DICOM (Digital Imaging and COmmunication in Medicine) was created as a protocol for image data and storage in a digital format, and is widely adopted for X-ray images, MR, CT, ultrasound images and other imaging modalities[26]. DICOM was published in 1993 and is continuously being extended ever since. In 1995, DICOM was accepted as a formal standard in Europe (MEDICOM, ENV 12052)[27]. The standard ENV 12052 Medical Informatics – Medical Imaging Communication is updated in 1997 by the CEN/TC 251 WG IV, and is still ongoing work on the standard with respect to Communication, workflow and data management[28].

With defining the DICOM Extensions in Supplement no 30 (2001), the standard also comprises non-image digital data related to a patient like ECG and other vital signs based on curve data recordings. The purpose is to maintain the recorded information in digital format (not a picture), which opens up for later measurements without loosing quality. With the implementation of time-stamps, correlations between digital images of for instance an angiographic examination can be visualized with simultaneous recording of cardiac pressure.

DICOM Working Group 1 - Cardiac and Vascular Information has undertaken a work task to develop a DICOM Supplement to address the robust interchange of waveform and related data in DICOM environment.

- The DICOM Supplement 30 is primarily intended for ECG-recordings, but is also open for other dynamic waveforms when acquired in a medical imaging environment. The recorded information is handled integrated into the DICOM protocol and based on the DICOM SOP-classes (Service-Object Pair Classes)[29].

DICOM SOP- classes defined

- 12-lead ECG
- General ECG Waveform Storage
- Ambulatory ECG

A non-technical introduction to the DICOM standard can be found on the web-site to RSNA[30].

[26] http://medical.nema.org/
[27] http://dicom.offis.de/dcmintro.php.en
[28] http://www.iso.org/iso/en/CatalogueDetailPage.CatalogueDetail?CSNUMBER=43218&scopelist=PROGRAMME
[29] DICOM Supplement 30: Waveform Interchange: http://medical.nema.org/Dicom/supps/sup30_lb.pdf
[30] http://www.rsna.org/Technology/DICOM/intro/index.cfm

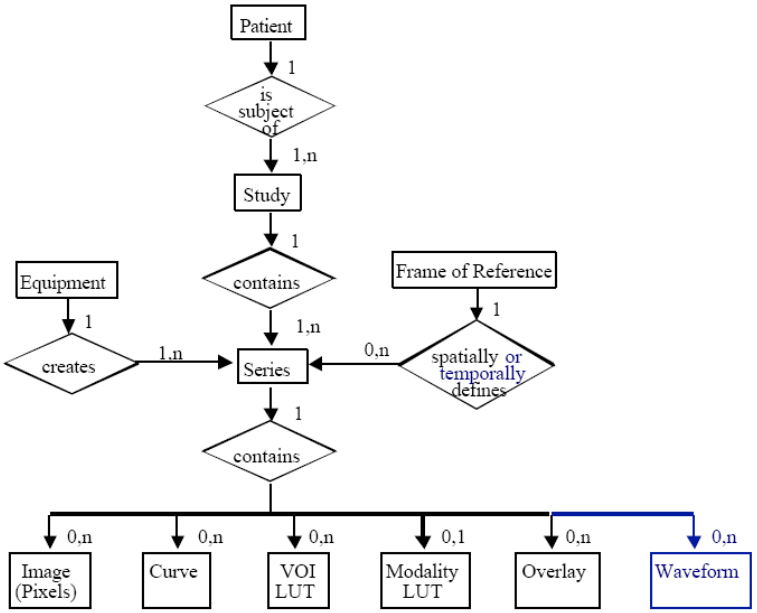


Figure 6 DICOM Composite Image IOD Information Model[29].

The Waveform information objects are incorporated in the image information objects, and the waveform object carries the raw waveform sample data. There are defined a coding schema for defining the waveform sequence, number of channels, sampling frequency and channel source as well as possibilities for waveform annotations.
The waveform sample formats are flexible (8 and 16 bit), signed or unsigned.

4.4.1 Scope of DICOM (from a DICOM Strategic Document)[31]

The goals of DICOM are to achieve compatibility and to improve workflow efficiency between imaging systems and other information systems in healthcare environments worldwide. DICOM is a cooperative standard. Therefore, connectivity works because vendors cooperate in testing via scheduled public demonstration, over the Internet, and during private test sessions.

4.4.1.1 Technology Overview

The DICOM Standard addresses multiple levels of the ISO OSI network model and provides support for the exchange of information on interchange media. DICOM currently defines an upper layer protocol (ULP) that is used over TCP/IP (independent of the physical network), messages, services, information objects and an association negotiation mechanism. These definitions ensure that any two implementations of a compatible set of services and information objects can effectively communicate.

At the application layer, the services and information objects address five primary areas of functionality:

- *Transmission and persistence of complete objects (such as images, waveforms and documents),*

[31] DICOM, Strategic Document, Version 5.1, December 5, 2005.
http://medical.nema.org/dicom/geninfo/Strategy.pdf

- *Query and retrieval of such objects,*
- *Performance of specific actions (such as printing images on film),*
- *Workflow management (support of worklists and status information) and*
- *Quality and consistency of image appearance (both for display and print).*

DICOM does not define an architecture for an entire system; nor does it specify functional requirements, beyond the behavior defined for specific services. For example, storage of image objects is defined in terms of what information must be transmitted and retained, not how images are displayed or annotated. An additional DICOM service is available to specify how the image must be presented with annotations to the user. DICOM can be considered as a standard for communication across the "boundaries" between heterogeneous or disparate applications, devices and systems.

4.4.2 DICOM's Relationship to Other Standards[31]

CEN has created and approved a normative reference to the DICOM standard in EN 12052, an official European Norm. In parallel, the convergence of a Japanese interchange media format (IS&C) with DICOM required much joint work where JIRA, the Japan Industries Association of Radiological Systems, played a major role. In the USA, DICOM participated in the early coordination efforts for healthcare standards with the ANSI-HISBB from which DICOM adopted a harmonized patient name structure, and started progressively to define links with HL7. This cooperation has now entered in a very active phase with the creation, in 1999, of a joint DICOM-HL7 working group. DICOM established a Type A liaison with the ISO Technical Committee 215 at its creation in 1999. ISO TC 215 has decided not to create an imaging working group, but to rely on DICOM for bio-medical imaging standards. It is foreseen that ISO will create and approve a standard that will reference the DICOM standard, as CEN has done. In 2003, the DICOM Standards Committee became a member of the E-health Standardization Coordination Group, a group endorsed by the ITU with the objective to promote a stronger coordination amongst the key players in the e-Health Standardization area.
Finally, DICOM has a strong relationship with IHE, the Integrating the Healthcare Enterprise initiative, where profiles of standards are defined as solutions for healthcare workflow and enterprise integration challenges.

4.4.2.1 DICOM Waveform Object Definitions

The Object Definitions is based on a Standard DICOM Composite Object Model, which is a hierarchical data organization with tagged variable length data elements. A DICOM MIME type is used for email attachment.[32]

Annotations part of the data acquisition may be included in the Waveform Object Instance

[32] Harry Solomon, Chairman DICOM Working Group 1 (Cardiovascular Information). http://www.fda.gov/cder/regulatory/ersr/ECGpresentations.htm

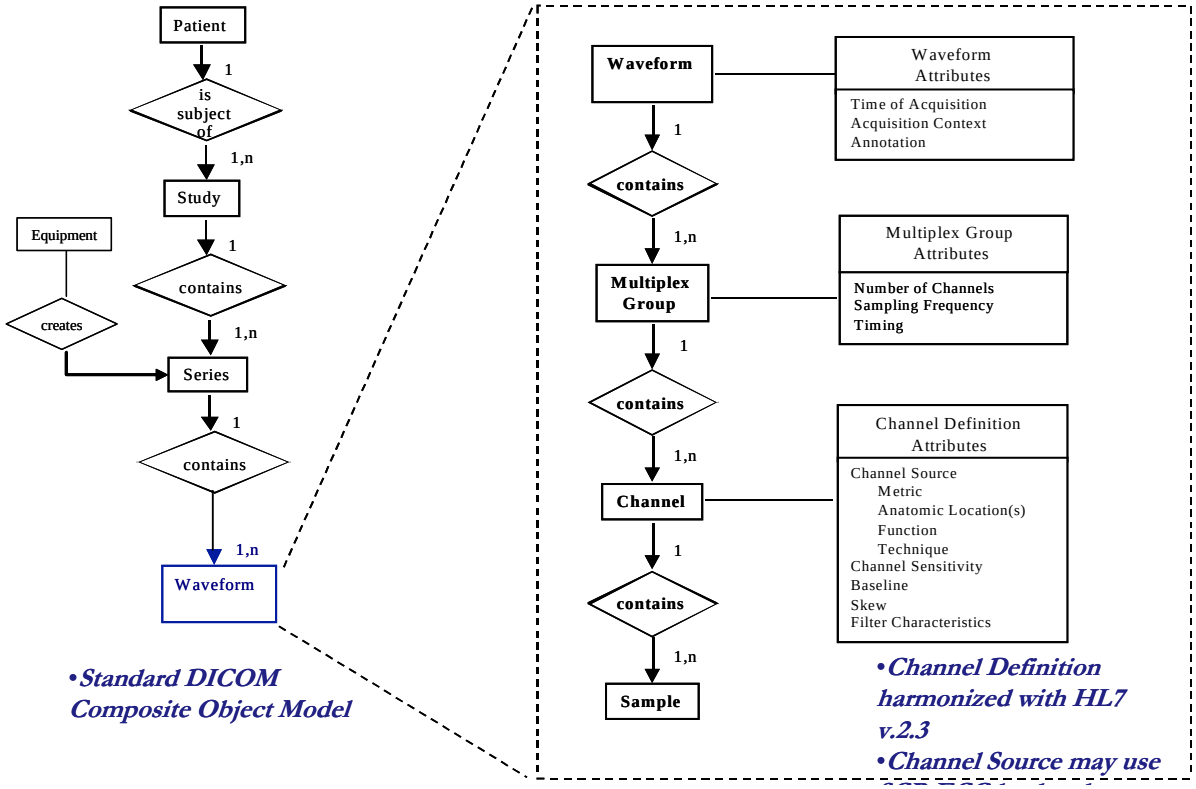


Figure 7Standard DICOM Compostie Object Model[32].

4.4.2.2 DICOM Waveform Interchange Standard

DICOM supports functions for 12-lead ECG recordings and long time series from Holter monitors.
It supports binary data values.
It is possible with Time Synchronization with images.
Annotations are supported in the same SOP structure as a DICOM Image Object.
The waveform is stored as an Image Object.

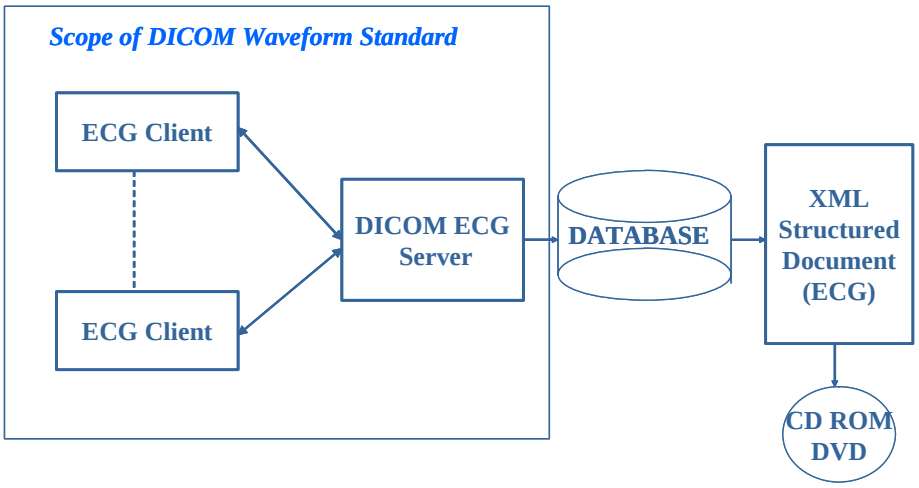


Figure 8DICOM Client-Sever structure[33]

[33] Figure from Suave Lobodzinski, Ph.D, Professor of Electrical and Biomedical Engineering California State University, Chief Scientist, iWay Corporation; http://www.fda.gov/cder/regulatory/ersr/ECGpresentations.htm

4.4.3 Evaluation of the standard

The DICOM standard is widely adopted as an image storage format and with the Supplemet no 30, this standard can also be used for storage of ECG-recordings or other vital sign parameters. If those recordings are performed in a relationship to an image examination, it is naturally to store those related information within the same format and standard.

It seems not naturally to use the DICOM format for storage of a standard 12-lead ECG-recording performed as a stand-alone recording where no images are taken.

Because of the relationships to DICOM SOP-classes, the file structure is quite complex, and is difficult to use in a wireless tele-medical service.
However, the DICOM framework for exchange of information is based on TCP/IP which is used in a local area network (LAN) within a hospital. Nevertheless the file seize and structure is evaluated as not particularly suited for a tele-medical solution even if this also is based on TCP/IP communication protocols.

If, however, the actual ECG recording is performed in accordance to medical investigations requiring a medical picture format, as for instance an ultrasound recording, the measurements can altogether be saved as a DICOM file, which by a tele-medical service can be transferred as a secure message to a hospital for diagnostic evaluations by a specialist.

4.5 Still picture formats

There are several image formats that can be used for storage and display of a standard 12-lead ECG recording, those will act as still picture formats and can only be able for viewing of the recorded information. It is not possible to retrieve the sampled values and perform analyses of the ECG-recordings with respect to arrhythmia and beat detections when the recordings are stored as a still picture format. Those formats can only be used to display the recordings on the same way as if it was printed on paper. In this chapter some actual raster formats are described and evaluated for use of storing and displaying ECG-recordings.

For a standard 12-lead ECG recording, it is possible to convert the recordings into a raster picture format, and this picture can easily be shown in a web-browser. Long time recordings can hardly be done, as the image format will be within 1 page size and if long time is used for the time-series (X-axis), the corresponding values on Y-axis will be quite small. However if an image viewer program is used this picture can be enlarged to show a proper representation of the ECG-recordings within a scrollable time-segment of the recordings.

4.5.1 GIF (Graphics Interchange Format)

The GIF format is widely used for pictures to be displayed in Internet browsers. This bitmap format supports 256 distinct colors, and is a compressed file format using the LZW data compression method (Lempel-Ziv-Welch – a lossless data compression algorithm). Originally GIF was introduced by CompuServe, but the LZW compression was covered of a patent by Unisys Corporation. From 2004 this patent has expired, and there is no patent license fee for the use of the GIF-format[34].

GIF is normally used for line drawings, diagrams, textual or icons graphics and presentations where there is an even area of colors. If a picture is to be converted to GIF, there will be some disturbances of the color representation.

4.5.2 JPEG (Joint Photographic Experts Group)

The JPEG (or JPG) is a commonly used standard for photographic images. The format is based on a method of lossy compression which is well suited for pictures (photos and paintings) as it uses 24 bit color depths.
JPG is widely used on Internet and the pictures can be displayed in standard browsers. However, there have been patents rights problems for the use of this standard, as the company Forgent Networks is claiming a patent, but this patent will expire in 2006[35].

In the same was as for a GIF-format, ECG-recordings can be stored in JPG-format.

An extended version, JPEG2000, uses a wavelet-based compression method, but is not yet adopted in web browsers.
The JPEG2000-format is adopted as an ISO-standard, ISO/IEC 15444-1:2000, with several additional parts, 15444-2, -3, -4, -5 and -6. This standard was published as an ISO standard 23.09-2004[36].

[34] http://en.wikipedia.org/wiki/GIF
[35] http://en.wikipedia.org/wiki/JPEG
[36] http://www.iso.org/iso/en/CombinedQueryResult.CombinedQueryResult?queryString=15444

4.5.3 PNG (Portable Network Graphics)

The PNG format is a losslessly compressed bitmap image format that originally was created to avoid the limitations of 8 bit color code in GIF images and at the same time avoid the patent fee problems[37]. The format was released as a single-image format in 1996 as RFC 2083, it became a W3C recommendation 01.10-1996 and 10.11-2003, and is now an ISO/IEC standard 15948:2003 published on 03.03-2004[38].

The format is supported by web-browsers, and is widely used for both pictures and icon graphics. It can offer transparencies and have a greater compression than GIF and better color depths. Normally the PNG format will have larger file sizes than a JPEG photo, but it will be a better choice for line art and images with text information.

4.5.4 TIFF (Tagged Image File Format)

TIFF is a file format for storing raster images of both photographic and line art types, and is widely used in publishing information either as a PostScript format (like PDF) or in printed publications. Graphic software mostly use TIFF format, because of the high color depth and the good image-manipulation support by most publishing software and page layout applications.

The TIFF format can handler multiple images in a singe file and it uses tags to define geometry, size, outlines etc. The image can be stores also in a compressed lossless format with a bi-level function mostly used for low-quality handling of the picture in the page layout program, and automatic functions for launching the ligh-quality picture for printing purposes.

The TIFF format gives normally a high file size, and the format is not supported by web-browsers. It is a public domain raster format, and specifications are available from Adobe[39].

4.5.5 PDF (Portable Document Format)

This format is not a picture format, but can easily be used for storing of all kind of 2D information in a standardized format developed for publishing information where the file should be displayed exactly as produced, independent of viewer systems or applications.

The format is developed by Adobe, and a lot of new extensions are developed[40].
PDF files can be used for representation of documents containing text, fonts, images and 2D vector graphics. Thus an ECG-recording stored as a bitmap picture can be converted into a PDF-document, which easily van be viewed in an application having support for PDF-formats.

[37] http://en.wikipedia.org/wiki/Png
[38] http://www.iso.org/iso/en/CatalogueDetailPage.CatalogueDetail?CSNUMBER=29581&ICS1=35&ICS2=140&ICS3=
[39] http://partners.adobe.com/public/developer/tiff/index.html
[40] http://partners.adobe.com/public/developer/pdf/index_reference.html

5 Other relevant standards

5.1 ISO/IEEE 11073-10101 Point-of-Care

Health informatics – Point-of-care medical device communication – part 10101:Nomenclature contains the VITAL nomenclature definition is not yet ratified as a standard. This work is an integrated part of the 11073-000000 Framework and related documents where the TC251 WG IV recently proposed a new definition in 11073-10102 Annotated ECG.
This is now continued in the ISO/IEEE 11073-10102 PoC – nomenclature-annotated ECG, trying to harmonize how ECG annotation information is identified. There is also established a joint work in the ISO/TC 251 WG7 (Devices) for plug-and-play interoperability at the point of care.
Terminology for ECG lead definitions are the same for the standards SCP-ECG, HL7 v3 and 11073, however, the diagnostic codes are not harmonized yet and will hopefully be completed in the proposed standard 11073-10102.

This nomenclature creates a data dictionary for present and future medical device data communications. It standardizes the language used and defines unique terms and concepts needed for point-of-care medical device data communication, especially for acute-care and patient vital signs.

The annotations normally used in ECG-recordings are defined by ISO/IEEE 11073-10101 Point-of-Care, which contains a comprehensive list of annotations. Types of annotations to be used are defined by:

- Beat
- Wave Component
- Rhythm
- Noise

Annotations are labels that point to specific locations within a recording and describe events at those locations. For example, many of the recordings that contain ECG signals have annotations that indicate the times of occurrence and types of each individual heart beat ("beat-by-beat annotations").

5.1.1 Beat annotations

According to IEEE 11073-10101, the most actual beat annotations to be used are in Table 4 defined with annotation codes used by the PhysioBank (MIT) arrhythmia database[41].

Table 4 Annotations classification with corresponding codes.

Code	Beat Rhythm	Sub-classification
N	Normal	
	Abnormal	
S	Supraventricular premature	
A		Atrial premature
J		Junctional (nodal) premature
A	Aberrated atrial premature	

[41] http://www.physionet.org/physiobank/annotations.shtml

	Non-conducted p-wave	
V	Premature ventricular	
F		Fusion
R		R on T
N	Supraventricular escape	
E		Atrial escape
J		Juctional (nodal) escape
E	Ventricular escape	
	Pre-excitation	
		Wolf-Parkinson-White
		WPW type A
		WPW type B
		Lown-Ganong-Levine
B	Bundle branch block	
L		Left bundle branch block
		Incomplete left bundle branch block
R		Right bundle branch block
		Incomplete right bundle branch block
		Left anterior fascicular block
		Left posterior fascicular block
		Bifascicular block
		Trifascicular block
		Bilateral bundle-branch block
		Intraventricular conduction disturbance
/	Paced beat	
F	Pacemaker fusion beat	
Q or ?	Unknown	

5.1.2 Waveform components

According to IEEE 11073-10101, there are several possible wave components, and for instance the annotations used by the FDA-MXL standard normally describe the wave component onset time and offset time. (P-wave onset-offset, QRS complex onset-offset). However there are alternatives for defining different parts of the waveform components. For instance the actual wave onset can be defined (P-wave-onset) or the offset can be defined (T-wave-offset). The peak value can be defined as the absolute time given at the peak (R-wave-abs.time).
The most actual waveform components and calculations to be used by arrhythmia detectors are given in Table 5.

Table 5 Waveform components with corresponding codes.

Code	Wave component	Remarks
{RoI	Region of Interest	A selected part of the ECG-curve (one beat)
{Q_{onset}	Q-wave point	Defined with onset timestamp
{R_{peak}	R-wave peak	Defined with absolute timestamp
{S_{offset}	S-wave point	Defined with offset timestamp
{T_{peak}	T-wave peak detected	Defined with absolute timestamp
{T_{offset}	T-wave end point detected	Defined with offset timestamp

{QRS	QRS width detected	Defined with onset-offset timestamp
{QRST	QRST width detected	Defined with onset-offset timestamp
{QT_C	QT width normalized	Calculated using Bazetts formula (in msec)
{QR_{slope}	R-wave Slope	Calculated based on the Y_n values
{RR	R-R interval	Calculated based on the last R-wave detected

5.1.3 Rhythm annotations

The most commonly used rhythm annotation strings are given in Table 6 Waveform components with corresponding codes[42].

Table 6 Waveform components with corresponding codes.

String	Description
(AB	Atrial bigeminy
(AFIB	Atrial fibrillation
(AFL	Atrial flutter
(B	Ventricular bigeminy
(BII	2° heart block
(IVR	Idioventricular rhythm
(N	Normal sinus rhythm
(NOD	Nodal (A-V junctional) rhythm
(P	Paced rhythm
(PREX	Pre-excitation (WPW)
(SBR	Sinus bradycardia
(SVTA	Supraventricular tachyarrhythmia
(T	Ventricular trigeminy
(VFL	Ventricular flutter
(VT	Ventricular tachycardia

[42] http://www.physionet.org/physiobank/annotations.shtml

5.2 ISO CEN TC251/ PT-40/NO1-16

5.2.1 ENV 14271 - File Exchange Format for Vital Signs

Under the CEN/TC 251 Working Group IV, Project Team 40, a proposed standard "File Exchange Format for Vital Signs" is sent on request for comments in 22nd of February 2001[43], this was published by the CEN/TC251 at 18.12-2001, and an updated version of 22.11-2002 is available.

CEN/TC251/PT-40, File Exchange Format for Vital Signs, Revision 1.2, 22.2.2001[44].

This proposal was approved as ISO 11073-20401 Health informatics – Point-of-care medical device communication – Application profile – File exchange, as a Standard for saving vital signs data (per CEN ENV13734) in a static file structure ENV 14271:2001 (IEEE 1073.2.4.1).

The following information is from the revision 1.2:

This prestandard provides the specification for an universal File Exchange Format within the domain of healthcare containing demographic data, administrative data and medical information ("Vital Signs Information").
This prestandard is based upon the results of long expert discussion and practical experience in clinical work and international co-operation projects where the requirements for specification of a standard File Exchange Format for biosignals have emerged. Based upon all this previous work and based upon the previous standard for Vital Signs Information Representation (ENV 13734) this object oriented standardization proposal is presented. Its details are described in the following chapters.

This standard covers the off-line storage of biosignals, time-stamped measurements, events, enumerations and alerts as expressed in the CEN/TC251 prestandard Vital Signs Information Representation (ENV 13734). This standard defines a file data structure and not a message data structure. This standard does not support data compression. This standard includes a method to encapsulate or refer to one or many medical images, digital video and audio files but the intention is neither to define a new format for medical or other images, video nor audio.

The file exchange format (FEF) is applicable to computer systems used in medical applications independent of the specific hardware technology. The FEF specification covers all vital signs information which was described within the VITAL domain information model.

The FEF has to be organised in sessions of vital signs data acquisition. Several session tests of vital signs data acquisition form a session archive. One or more session archives are available for each patient. Never should one session archive contain information for more than one patient. This results already in a specific restricted view on the VITAL domain information model.

[43] http://www.tc251wgiv.nhs.uk/pages/docs/fef_fwd.zip
[44] http://www.tc251wgiv.nhs.uk/pages/docs/fef_fwd.zip

6 Challenges in wireless biomedical transmission systems

6.1 Tele-home-care solutions

Available equipment at the market makes it possible for the patient in their home, to take a daily ECG-recording and transmit the signal to the doctor at the hospital for follow-up. Even if this is a 12-lead recording, it is only some seconds of sampled values to be transmitted as a digital file, which easily is transmitted as a "normal" data-communication solution without any problems related to communication speed and capacity.

If, however, the patient is wearing a wireless ECG-recording system, there are several challenges to perform a reliably transmission solution by the use of standard telecom-munication systems. To obtain a solution for continuous ECG-recording in situations for early diagnostic purposes or to follow up patients after hospital treatment, new solutions for Tele-home-care services have been developed by the Norwegian company WPR Medical AS[45].

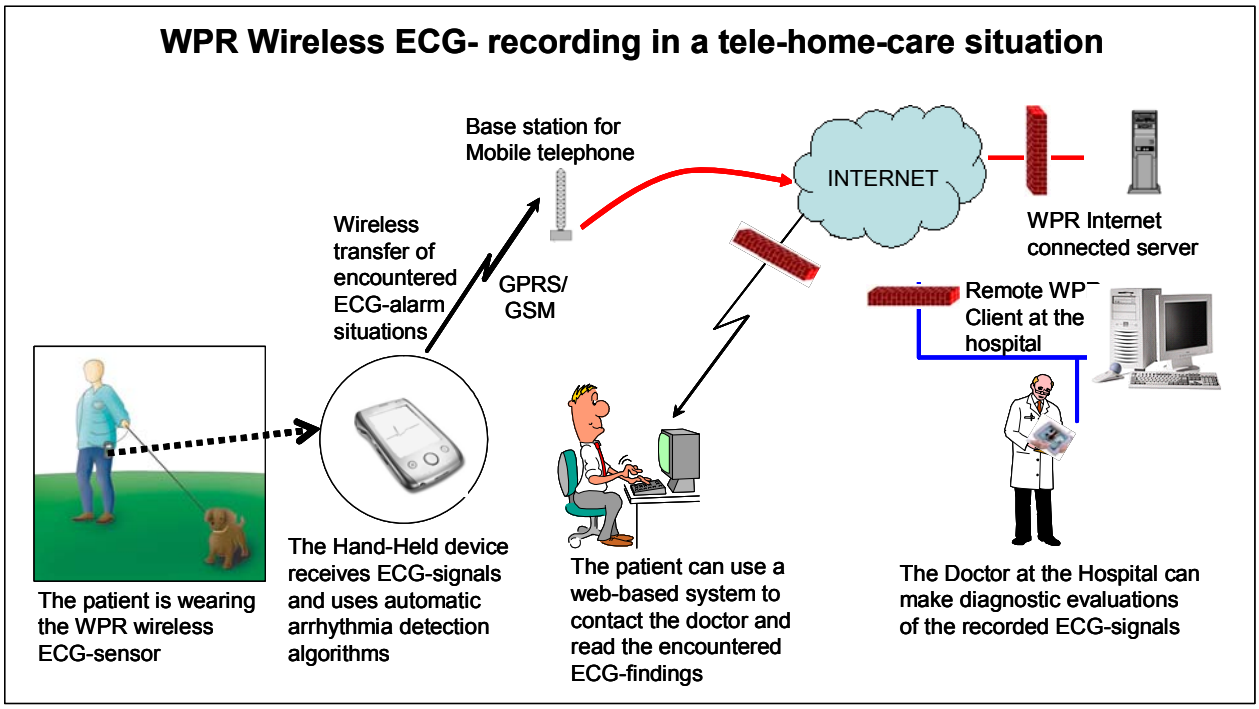


Figure 9Wireless ECG-monitoring for patients' out-of-hospitals[45].

In this tele-home-care scenario, the patient will be wearing a wireless sensor which communicates with a corresponding "Hand-held device". WPR Medical is developing a solution intended for patients' out-of-hospitals, where the Hand-held device have incorporated arrhythmia detection algorithms. When an un-normal situation is detected, this device will, by use of standard telecommunication solution like GPRS (General Packet Radio Service) transmit the recorded event to a corresponding server to be located at the hospital.

[45] R. Fensli, E. Gunnarson, and T. Gundersen, "A Wearable ECG-recording System for Continuous Arrhythmia Monitoring in a Wireless Tele-Home-Care Situation," presented at The 18th IEEE International Symposium on Computer-Based Medical Systems, Dublin, Ireland, 2005.

6.2 Body Area Network - BAN

The situation for a wireless bio-medical sensor is to operate within a “body-area-sensor-network” and with a high signal throughput to the corresponding Hand-held device. Today, only a few solutions of wireless remote monitoring systems are developed for research purposes and no known products available at the market by February 2006. Because of a lack of international standards for bio-medical sensors, the body-area-sensor-networks are developed as proprietary solutions, and the manufacture have to take necessary care of the security and reliability issues for this wireless transfer of measured data from patients.

Several international papers have focused on Body Area Network (BAN), and some information can be found at Fraunhofer-Gesellschaft[46]. However newer radio-transmission solutions have been developed during the past two to three years, and with improved specifications especially with respect to reliability in transmission with a high bit-rate throughput, and with the possibility to have a plurality of wireless sensors not disturbing for each other. Components and protocols like Bluetooth, ZigBee, RF-radio (2,4 GHz) are used in several international projects, without any kind of co-operation in the signal formats.

Because of a relatively limited range between the wireless sensor on the patient and the hand-held-device, normally 2-20 meters, it is not important to give recommendations or develop international standards for this communication link, unless it is important to have sensors from different vendors operating at the same time on the same patient. A more pragmatic approach is to let the different vendors take the responsibility to perform adequate reliability and security in this wireless link, and where precautions are taken to obtain privacy in the information transmitted.

The important aspects are, however, to define some standards for the wireless telecom-munication from the patient’s hand-held-device and to a server located at the hospital. There will be some limitations in the telecommunication protocols to be taken care of, and those limitations can give requirements with respect to the data format for the recorded signals to be transmitted as a tele-medical service.

6.3 Telecommunication systems

GPRS is a wireless communication system intended for high-speed data transfer, and it uses the internet-based protocols TCP/IP and HTTP or FTP for file-transfer. There can be situations where a security solution is required for instance if patient sensitive data is to be transmitted. Protocols like SSL or IPSec can be used for data protection, and dependant on the operating system on the hand-held-device, it can be established an encrypted VPN-tunnel (Virtual Private Network) from the hand-held-device to the server at the hospital. However, if the file to be transmitted only contains a reference ID and not personal related information of the patient; there will probably not be a need of data encryption. Nevertheless it might be necessary to protect the privacy of the patient; especially if location based information is to be transmitted together with the patient’s vital signs recordings.

The high-speed data transfer is in GPRS defined within different classes, and with variable up-link and down-link capacity. When a recorded ECG-signal is to be transmitted, one has to take into account both the file size and time for successfully transmission of this file. Depending upon the storage format for an ECG-recorded file, the file-size can be quite different, and it is supposed that 1-lead ECG recording of 1 minute can be stored in a file of about 60 KB if the MFER format or SCP-ECG format is used, and will be about 150 KB if the

[46] http://www.ban.fraunhofer.de/system/index.html

FDA-XML format is used (see more details in chapter 4). In Table 7, there are some estimated values for file transfer-time in a GPRS system, but the transmission parameters can give reduced capacity in situations with poor radio coverage.

In order to perform a continuous event recording system for ECG as a “Holter monitor” solution, an event of 1 minute ECG recording should easily be transferred in less than one minute for not making any obstacles in the system performance. As can be seen from table Table 7, this can be difficult to obtain unless the MFER or SCP-ECG format is used.

Table 7 Estimation of transmission time for 1 minute of 1-lead ECG-recording in GPRS data-transmission.

GPRS class	Sending slots	Up-load speed[47]	MFER standard SCP-ECG standard	FDA-XML standard
8	1	9 – 13 Kb/s	60 sec	150 sec
10	2	18 – 26 Kb/s	30 sec	75 sec
12	4	36 – 53 Kb/s	15 sec	40 sec

It should be noticed that in this estimated values, the GPRS communication link is supposed to be connected continuously. If, however, the system needs to establish the connection before the file transmission and to close down the link after file transmission, the time needed has to be increased with approximately 5-20 seconds.

The estimated values are calculated on basis of “normal expected” file size for 1-lead ECG-recording solution. If any other parameters are to be recorded, the file size will increase accordingly.

With respect to the security issues, a normal GPRS communication link will not perform any end-to-end encryptions. It is important to look at this communication link as unsafe when it comes to patient sensitive information, and to consider necessary precautions with respect to date integrity and confidentiality. Those aspects are not covered in this report, and the described standards for vital signs monitoring have no safeguard elements.

[47] Schiller, Johen: Mobile Communications. p 125. Addison-Wesley.2003. ISBN 0-321-12381-6.

7 Requirements for integration of Vital Signs recordings into Electronic Health Record

7.1 Archive formats in the Electronic Health Record systems

In the Norwegian health care sector, there are three different systems for Electronic Health Records (EHR) used in hospitals (DIPS, InfoMedix – Tieto Enator, DocuLive – Siemens), and three vendors with four different systems intended for the General Practitioner (Profdoc Norge, Infodoc and Hove Medical Systems). There are several vendors of solutions for secure communication (Well Diagnistics, Medlink, VismaUnique, Communicats). A project is recently started in order to define exchange of Vital Sings recorded messages within the Norwegian Health Network[48].

When the actual ECG-recordings is to be stored within the patient's EHR-system, one have to take into account the allowed file formats for long time storage in a EHR-system. The National Archival Services of Norway have defined some principles regarding file formats to be accepted for long-time archiving (cub clause 5.3.3[49]):

- The format should be documented as an open public description
- The format should be an ISO-standard
- There should be available and well established products in the market
- Converting to the archive format should be simple and easy
- It should be possible to convert information into the archive format from the normally used production formats
- It should be possible for future converting of documents from the archive format to new formats

Demands for archive formats are given by The Norwegian Centre for Informatics in Health and Social Care – KITH [50], which is according to the Noark-4 recommendations. According to Noark-4, chapter 14.3.3, p 82[51], and the requirement specification published at the web[52], the following formats are recommended:

• TEXT - ISO 8859-1:1987
• TIFF6 - TIFF versjon 6. (with LZW compression)
• SGML - SGML – ISO 8879:1986 (with subset HTML and XML)
• PDF - Portable Document Format

With respect to vital signs recording, the only actual standards accepted are the plain picture format TIFF, and the document format PDF. As described in chapter 4.5, it will not be possible to process any new arrhythmias or un-normalities detection of the waveform recorded based on those file formats, and they can only be used for display of the recorded waveform. Thus none of those formats can be used in a wireless tele-medical solution as described in chapter 6.3.
New formats for vital signs recording have to be accepted as archive formats, and those new formats should be based on the recommended principles for long-time archiving.

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[48] Prosjektbeskrivelse Meldinger med vedlegg. Nasjonalt senter for Telemedisin, juli 2005.
[49] NOARK-4. Norsk arkivsystem. Versjon 4.1. Del I: Funksjonsrettet beskrivelse og kravspesifikasjon. Oppdatert nettversjon 17.08.2005. http://www.arkivverket.no/noark-4/ny_noa_del1.pdf
[50] EPJ standard: Arkitektur, arkivering og tilgangsstyring. Del II: Tekniske spesifikasjoner. KITH 01.06-2001.
[51] NOARK-4. Norsk arkivsystem, Versjon 4.1. Del II: Tekniske spesifikasjoner. Oppdatert nettversjon 17.08-2005: http://www.arkivverket.no/noark-4/ny_noa_del2.pdf
[52] http://www.arkivverket.no/arkivverket/lover/elarkiv/noark-4/hva/del1/kap5.html

7.2 Standards for message exchange in the National Health Network

The Norwegian Centre for Informatics in Health and Social Care – KITH, has coordinated the work of standards for message exchange between health care organisations. This is described as a framework for message exchange (KITH rapport nr 25/02), which is based on the standard ebXML, based on ENV 13608-2 and -3[53].
The standards ENV 13608 Health informatics – Security for healthcare communication is ratified by CEN TC 251 and consists of the parts 13608-1 Concept and terminology, 13608-2 Secure data objects and 13608-3 Secure data channels[54].

A Norwegian draft of messages with attachments is proposed by Well Diagnostics in January 2006[55]. This draft is referring to the KITH reports for architecture, archiving and access control to Electronic Health Records (KITHEPJSTD[56]).

7.3 Recommended standards for a tele-medical system

There are yet no official evaluations of standards to be used in tele-medical services.

As described in chapter 4.5 the formats GIF, JPEG, PNG, TIFF and PDF are used for storage of 2D still picture images. It is thus not possible to retrieve an ECG-recording stored within one of those formats and be able to execute a new calculation of arrhythmias or beat detections, and thus a “second-opinion” after the original file of raw-data is converted to a picture format and stored in the EHR can not be performed.

In many tele-medical situations, the purpose of sending an ECG-recording to a hospital is to obtain a valid diagnostic evaluation done by a cardiology specialist. He will then need to use dedicated ECG-analyzing software capable of making measurements and perform arrhythmias and beat detections, and based on this store the actual sequences of the recordings into the EHR-system. This ECG-analyzing system should be capable of reading a standard ECG-recordings stored in desired format as one of the international standards described in chapter 4.

As a principle, formats defined as international standards are described and open available, and should be considered as acceptable even for long-time storage where the challenge will be to continue to use this format for many years to come. Based on the principles stated in chapter 7.1, all the four actual standards for ECG and vital signs recording should be accepted as a storage format; SCP-ECG, MFER, FDA-XML, DICOM.

If one of those standards is used by one hospital, it should be possible to send the recorded file to another hospital or to the General Practitioner as a secure message within the National Health Network. The transfer of this recorded information should be based on the principles for secure message exchange as described in chapter 7.2, where the actual file is sent as an attachment to an ebXML-based message.

In order to be a general solution, this will require different file converters in order to convert an actual ECG-recording to and from the desired file format. However, there are already several converters freely available or as licensed software.
All EHR systems should also have incorporated actual file viewers in order to properly display the actual vital signs recording stored in the desired file format.

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[53] http://www.kith.no/upload/1073/R25-02RammeverkMeldingsutveksling.pdf
[54] http://www.centc251.org/
[55] Well Diagnostics: Nasjonale retningslinjer – meldinger med vedlegg. Versjon 0.5, 16.01-2006.
[56] http://www.kith.no/templates/kith_WebPage____834.aspx

8 Recommendations and guidelines

8.1 Wireless Body Area Networks

In a wireless Body Area Network, BAN, there will in the near future be a plurality of wireless sensors placed both on the surface of body or inside the body for vital signs measurements, communicating to a patient's Hand-Held-device which acts as a common processing unit and a gateway for transmission of the measured signals to other monitoring solutions.

For the BAN, some design proposals are developed, and several different solutions can be used for the lower layer protocols like Bluetooth (IEEE 802.15.1), the High-Rate WPAN (IEEE 802.15.3) and ZigBee (IEEE 802.15.4) or general RF-radio communication solutions (868 MHz, 2,4 GHz).

There exists no common standard at the application layer for the signals to be measured, and in order to achieve optimum performance in the measuring solutions, there will in the future probably exist several proprietary solutions and file formats.

Because of the limitations both with respect to the wireless areas covered around the patient by the local transmission system and the processing capacity of a Hand-Held-Device, it will be advisable in the future to give the vendors the responsibility of to perform adequate reliability and security in this wireless link, where necessary precautions are taken to obtain privacy and reliability in the information transmitted.

At the time being, there should not be given any strict regulations to this wireless BAN solution. However, future recommendations can be developed based on market trends, but this work should not be started until the use of such solutions are widely tried out in realistic clinical trials and adopted in the market.

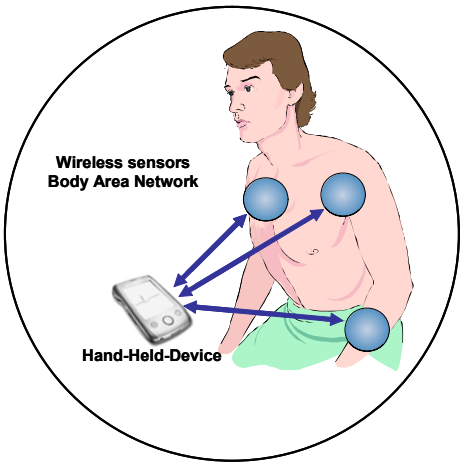

Figure 10 Typical Body Area Network with multiple sensors communicating to a Hand-held-device.

8.2 Telecommunication solutions

For the telecommunication solution from the patient's Hand-Held-device and to the hospital, the transfer of information should be within a secure and reliable transmission framework as the National Health Network, NHN.

From the telecom operators Mobile Base station, there will probably be a gateway for connection to Internet, and a secure information transfer will normally have to be established from the Hand-Held-Device to a Data server located within a hospitals network, as indicated in Figure 11. The doctor at the hospital will probably be using a "clinical application" on his workstation, in order to retrieve the transmitted information from the patient and to view the recorded measurements.

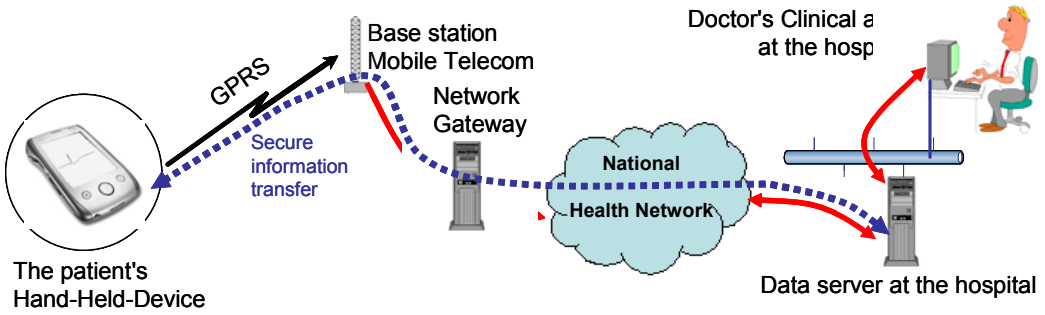

Figure 11 Wireless tele-communication solution from the patient's Hand-Held-Device to a data-server within the national Health Network.

In order to achieve a standard solution for the transfer of the recorded vital signs parameters, there should be given some recommendations of accepted standards to be followed.

As described in chapter 6.3, because of the limitations both in the transmission speed and in the processing capacity of a mobile device, only the international standards anticipated to be used in this telecommunication link are the MFER and SCP-ECG standards. However, as described in chapter 4.1 the SCP-ECG format is not intended for long-time series of ECG recording as a "Holter monitor" solution. *This limits the proper file system to be used in a wireless tele-medical service to the MFER standard as the only acceptable solution.*

In addition to the use of a standard format for the recorded vital signs information, necessary precautions should be taken with respect to data integrity and confidentiality in this wireless link. It is, however, because of limitations in the mobile unit, not possible to use the requirements for message transfer within the NHN which is based on ebXML massages. It is therefore necessary for the actual solution to be implemented, to define a proper security model for the file transfer from the mobile device to the data server. The security issues are not described in this report, the focus is only on the file formats used for the recording, transmission and storage of vital signs signal within the framework of a tele-medical service.

The doctor's workstation can be located within the hospital, where the data server and the workstation can be within the same Local Area Network, and the security precautions would be according to the hospitals requirements and policy.

When the doctor has performed the necessary analyses and made the actual documentation both of annotations and the epicrises, this information should be stored as a document within the patients EHR at the hospital. Thus the EHR system should be able to import the stored recordings of the vital signs information together with the epicrises, and correspondingly the doctors' clinical application should be able to export those files in a standard format.

8.3 Integrations within the EHR systems

There are requirements with respect to accepted file formats in a long-time storage system like the patient's EHR. Based on the requirements given in chapter 7.1, and the necessity of using an established international standard for the vital signs recording, several new formats should be accepted as an archive format.
It is necessary to archive vital signs recording in a format where it in the future can be possible to make new calculations based on the curve form, and all the international standards evaluated in this report will probably comply to the requirements given by the NOARK recommendations. There might also be a need of some simple still-picture formats just for displaying the recorded information, and the well established standards described in chapter 4.5 should be recommended.

Based on those assumptions, the following standards should be accepted to be used in an EHR system as a long-time archive format (in addition to the already accepted formats TIFF and PDF):

- CEN ENV 1064 – SCP-ECG
- ISO/WD 11073 90201 – MFER
- ANSI/HL7 V3 Annotated ECG (FDA_XML)
- ENV 12052 Medical Imaging, DICOM Supplement 30
- ISO/IEC 15444-1:2000 JPEG2000 (in addition also JPEG)
- ISO/IEC 15948:203 PNG

Not all of these standards are accepted as international standards yet; they are at different draft levels and precautions should be taken with respect to future changes.
All EHR systems should be able to import a file stored in one of those formats and store this file in the patient´s EHR either as a document or as a fragment, and should have incorporated a proper viewer solution in order to be able to display the information from the recorded vital signs monitoring systems.

8.4 Messages sent between health care services

When a message is to be transmitted from the hospital to the General Practitioner and vice-versa, or from one hospital to another, the message should be a secure ebXML message with the actual recorded file (stored in one of the formats recommended in chapter 8.3) as an attachment, according to the recommendations from KITH[56] and the description by Well Diagnostics, January 2006[57].

This will require that the ebXML-message have a RefDoc structure with extended MIME-types defining the actual file type used.
Suggested MIME-types based on the recommended file formats for vital signs recording:

- application/scpecg
- application/mfer
- application/fdaxml
- application/dicom
- image/jpeg
- image/png

In order to comply with the requirements given for attachments to an ebXML message, the identification of the attached file should have a unique ID of type GUID. This principle need to be implemented when the actual file is stored at the data server at the hospital, as described in chapter 8.2.

[57] Well Diagnostics: Nasjonale retningslinjer – meldinger med vedlegg. Versjon 0.5, 16.01-2006.

9 References

[1] R. Fensli, E. Gunnarson, and T. Gundersen, "A Wearable ECG-recording System for Continuous Arrhythmia Monitoring in a Wireless Tele-Home-Care Situation," presented at The 18th IEEE International Symposium on Computer-Based Medical Systems, Dublin, Ireland, 2005.

[2] CEN/TC 251 is prEN 1064:2005 (E), Health informatics — Standard communication protocol — Computer-assisted electrocardiography.

[3] ISO/TC 215/WG2.1 WD 11073-90201 Health informatics — Medical waveform format — Encoding rules (MFER), 20.10-2004.

[4] ANSI/HL7 V3 ECG, R1-2004, Health Level Seven Version 3 Standard: Regulated Studies - Annotated ECG, Release 1 (new standard): 5/6/2004

[5] Digital Imaging and Communications in Medicine (DICOM), Supplement 30: Waveform Interchange. DICOM Standards Committee, Working Group 1 - Cardiac and Vascular Information. 1 November 1999.

[6] Prosjektbeskrivelse Meldinger med vedlegg. Nasjonalt senter for Telemedisin, juli 2005.

[7] EPJ standard: Arkitektur, arkivering og tilgangsstyring. KITH 01.06.2001 (KITHEPJSTD).

[8] Well Diagnostics: Nasjonale retningslinjer – meldinger med vedlegg. Versjon 0.5, 16.01-2006.